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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,415	05/16/2001	Falk Fish	FISH4	9137

1444 7590 05/13/2004

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,415

Applicant(s)

FISH, FALK

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 1, 2004 has been entered.

Amendment Entry

2. The amendment filed April 1, 2004 has been entered. Claims 1,4,6 and 9-10 have been amended. Claims 3 and 11 have been cancelled. Claims 1-2, 4-10 and 12 are under consideration in the office action.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The rejection of claims 6-12 under 35 U.S.C. 112, first paragraph;
- b) The rejection of claims 1-6, 9 and 11 under 35 U.S.C. 112, second paragraph.

Response to Arguments

4. Applicant's arguments, filed April 1, 2004 with respect to the rejections of claims 1-2 and 4-5 have been fully considered however the arguments are not persuasive for the following reasons.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 1-2 and 4-5 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record. The rejection was on the grounds that the specification, while being enabling for a method for determining the level of glucose and hemoglobin in a sample obtained from a hair follicle, saliva or urine from an individual comprising: obtaining a sample from the individual; wherein the hair sample is washed and incubated in red cell lysing agent; two aliquots of sample are prepared: sample A is used to determine the level of glucose in the obtained blood or interstitial fluid after it is mixed with glucose oxidase, horseradish peroxidase and luminol and then placed in a luminometer which detects the amount of luminescence while sample B is used to determine the level of hemoglobin in the blood and interstitial fluid obtained from the hair sample as determined by the luminometer and finally the levels of glucose and hemoglobin in the sample are calculated using the net glucose reaction and calibrated equations comparing the ratio of glucose to hemoglobin, does not reasonably provide enablement for a method for determining the level of glucose in the blood of an individual comprising: obtaining a sample of hair or urine from an individual, said sample being a non-blood sample but containing blood components; determining the volume of blood in the obtained sample by measuring the

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level of a blood component in said sample; determining the amount of glucose in the sample or in the blood cells present in the sample and calculating the level of glucose in the sample.

Applicant asserts that the amendments limiting the claims to determining the level of glucose obviates the rejection. However, it is the examiner's position that determining the level of glucose in the blood of an individual by the claimed method does not overcome the scope of enablement rejection. The rejection is maintained because the claims generically recite measuring the level of blood components without reciting that the only blood components applicants measured was hemoglobin. The art, as evidenced by references A-I teach great variability in the analysis, which would lead to unexpected results requiring undue experimentation. Thus the prior art fail to support applicants' assertion that one skilled in the art could determine the level of glucose in the blood of an individual by the claimed method.

It is noted the correlation of glucose on hair and in blood are not recited in the rejected method claims and the claims are significantly broader and encompass the determination^{of} any blood component and calculating the level of glucose in the blood of the tested individual. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The specification, teaches the determination of the level of glucose and hemoglobin in a sample obtained from a hair follicle or urine using a luminescent method or lysis method, but the specification does not teach how to determine the volume of blood in the obtained sample by measuring the level of any blood component in the sample. The claims broadly recite determining the level of glucose in the blood by measuring the level of any blood component in

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the sample. However, neither the claims nor the specification recite method steps determining the level of every possible blood component from the samples. Furthermore, there is no teaching that the level of blood component found in the sample correlates to the amount of glucose found in the blood of an individual. Finally, the instant claims fail to recite all of the necessary method steps and reagents required to determine the level of glucose and hemoglobin in the sample. Therefore, the claims are not enabled for a method for determining the level of glucose in the blood of an individual.

The method of claim 4 indirectly determining the amount of glucose in either interstitial fluid or blood obtained from the hair or urine sample and compares the total amount of interstitial fluid or blood from which the glucose was extracted. Steps (ii) and (iii) of claim 4 alternatively claim determining levels in interstitial fluid while step (iv) recites calculating the level of glucose in the blood of the tested individual. Applicants' have not clarified how a skilled artisan can use only determinations of interstitial fluid to calculate or compare the level of glucose in the tested blood of an individual. Applicants' assertion that the alternative claim language obviates the rejection is not persuasive because both forms of the claim need to be enabled. There is no teaching of how to determine the level of glucose in the blood after determining level or concentration in interstitial fluid. The specification fails to provide guidance on such methods, thus in view of the unpredictability for determining the level of glucose in blood based on the determination of interstitial fluid, one skilled in the art could not use the broadly claimed invention without undue experimentation. Therefore, applicants' assertions are not persuasive.

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It is the examiner's position that applicants have no support that the determination of glucose levels in will correlate with the amount of interstitial fluid from the sample. Given the lack of guidance contained in the specification, one of skill in the art could not make or use the broad claimed invention without undue experimentation. Thus, one of skill in the art would have to locate de novo steps required for a method of determining the level of glucose in the blood as determined by the level of blood component or interstitial fluid. There is no guidance as to what blood components, besides hemoglobin, can be analyzed using this method. Moreover, there is no requirement for the use of detectable reagents that would determine the level of glucose or blood component in a sample. Given the lack of guidance contained in the specification and the unpredictability for determining the level of glucose in the blood an individual based upon determining the level of any blood component or amount of interstitial fluid in the sample, one skilled in the art could not use the broadly claimed invention without undue experimentation. Therefore in view of reasons stated above, the rejection is maintained.

Claim Rejections - 35 USC § 112.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claims 7 and 8 recite the limitation "said red blood cells" in the claims. There is insufficient antecedent basis for this limitation in the claim.

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8. Claim 10 is drawn to a kit that comprises a suitable diluent. The term "suitable diluent" in claim is a relative term which renders the claim indefinite. The term "suitable diluent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term cannot be ascertained. There is no teaching of what makes a diluent suitable. Neither is there a teaching of what diluents can or cannot be used with the kit. Therefore clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Paisey et al. The claims are drawn to a kit which comprises a means for obtaining a hair sample; a means for measuring the level of blood components; separation means; and a means for measuring the level of blood component and glucose; and a means for calculation. The dependant claims are drawn to separation means and suitable diluents.

Paisey et al., teach glycosylation of hair and the measure of chronic hyperglycaemia. The authors took hair samples from patients wherein the hair was taken from behind the ear and cut into 100mg samples (page 670). Therefore Paisey et al., teach a means for obtaining hair or urine samples. The patients also had blood taken for measurement of glycosylated haemoglobin

(page 670). The hair samples were incubated with thiobarbituric acid solution, distilled water, azide solutions, and guanidinium hydrochloride (page 670). Also serial dilutions of hexoses, glucose, galactose, sialic acid, mannose and arabinose were performed (page 670). Thereby teaching suitable diluents in which the blood obtained from the hair samples were diluted in. Also the authors inherently teach separation of red blood cells from the blood sample in order to determine the glycosylated haemoglobin concentration (page 669). A means for measuring the level of a blood component such as haemoglobin in the sample was achieved by agar gel electrophoresis (page 670). Gas-liquid chromatography analyzed sugar in the samples (page 670). Centrifugation techniques are also taught (page 670). The authors also note that glucose may be bound to the mature hair shaft from sweat and other extraneous substances (page 671). A means for calculating the level of glucose in the blood of the sample was based on the statistical results achieved by evaluating the statistical differences and regression analysis (page 670).

Table 1 glycosylation of samples of scalp hair from normal and diabetic subjects.

It is noted that the components in a kit are commercially available which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose a kit, it is inherently obvious to any one of ordinary skill in the art to create a kit comprising the recited components to determine the level of glucose in a sample and achieve economic efficiency.


Therefore, Paisey et al., teach components which meets the limitations of the claims by teaching a means for obtaining a hair sample; a means for measuring the level of a blood components; separation means; and a means for measuring the level of blood component and glucose; and a means for calculation just as claimed.

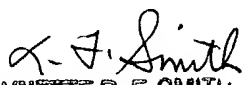
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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines 
May 4, 2004


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